

Related Change Request (CR) #: 3705

MLN Matters Number: MM3705

Related CR Release Date: March 30, 2005

Related CR Transmittal #: 27 and 513

Effective Date: December 17, 2004

Implementation Date: February 18, 2005

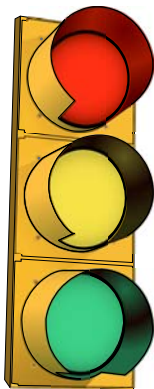
## *Infusion Pumps: C-Peptide Levels as a Criterion for Use*

**Note:** This article was revised to contain Web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

### Provider Types Affected

Physicians, suppliers, and providers providing continuous subcutaneous insulin infusion and related drugs/supplies in the treatment of diabetic patients in the home setting and billing Medicare carriers or Fiscal Intermediaries (FIs)

### Provider Action Needed



#### **STOP – Impact to You**

This article and related CR 3705 adds beta cell autoantibody testing as an alternative diagnostic per the updated C-peptide testing requirement for the use of insulin infusion pumps, effective for services performed on or after December 17, 2004.

#### **CAUTION – What You Need to Know**

Providers/suppliers treating Medicare diabetic patients with infusion pumps should be aware of this new Medicare coverage policy.

#### **GO – What You Need to Do**

Ensure that your staff is aware of this new coverage and that they bill according to the information in this article.

### Background

On August 26, 1999, the Centers for Medicare & Medicaid Services (CMS) issued the first decision memorandum (DM) for continuous subcutaneous insulin infusion pumps (CSII) that utilized a C-peptide testing requirement for Medicare coverage of CSII pump therapy. On May 11, 2001, CMS issued a second DM for insulin pump: "C-Peptide Levels as a Criterion for Use," and on January 1, 2002, CMS revised the laboratory value for the C-peptide testing requirement for Medicare coverage of CSII pump therapy.

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Effective for services performed on or after December 17, 2004, in addition to meeting criterion A or B, the beneficiary with diabetes must be insulinopenic per the fasting C-peptide testing requirement or, as an alternative must be beta cell autoantibody positive.

Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine)  $\leq 50$  ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.

CMS establishes that fasting C-peptide levels will only be considered valid when a concurrently obtained fasting glucose is  $\leq 225$  mg/dL.

Levels need only be documented once in the patient's medical records.

Coverage of all other uses of CSII that adheres with the Category B IDE clinical trials regulation (42 CFR 405.201) or routine cost under the clinical trials policy (Medicare NCD Manual Chapter 1, Part 4, Section 310.1) will continue.

Those billing for these services should note that Medicare carriers/intermediaries will accept, effective for services on or after December 17, 2004, CPT code 84681 (C-peptide) or CPT code 86337 (insulin antibodies) when diagnosis codes 250.00-250.93 are also reported on a claim.

### Additional Information

The official instruction issued to your Medicare carrier/intermediary regarding this change may be found by going to <http://www.cms.hhs.gov/transmittals/downloads/R513CP.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R27NCD.pdf> on the CMS web site.

If you have questions regarding this issue, contact your carrier/intermediary on their toll free number, which is available at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.pdf> on the CMS web site.

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